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10/599,907	10/13/2006	Pavak R. Mehta	GEN 3.3-014	6487

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EXAMINER	
WORSHAM, JESSICA N	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,907	MEHTA ET AL.	
	Examiner	Art Unit	
	JESSICA WORSHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application

1. The new Examiner of record acknowledges the receipt of the Amendment/Request for Reconsideration filed January 28, 2011.

Claims 1-23 are pending in this action. No amendments to the claims have been made herein. Claims 1-23 remain rejected.

Claim Rejections – 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1, 2 and 6-8 are again rejected under 35 U.S.C. 102(e) as being anticipated by Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250).**

Batycky *et al.* ('250) discloses particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs

without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

The particles of the invention have a mean particle size of about 5 to about 50 microns (p. 3, [0029]). The morphology of the instant particles contributes to enhanced dispersibility and stability by decreasing the area of contact between the particles (p. 3, [0030]). The particles can deliver at least about 5 mg of the drug and the powder can be compressed about 10 to about 29 times. Even when compressed, the particles still retain the improvement in dissolution rate (p. 3, [0030]). Suitable excipients for use in the formulation are disclosed at p. 4, [0035-0037].

In one embodiment, the invention provides for an important feature for conferring pharamacokinetic/pharmacodynamic solubility to a poorly soluble drug, whereby the feature is dissolving a crystalline drug to form a solution and spray drying the solution thereby making the drug amorphous and small without damaging bioactivity and concurrently making the particle comprising the amorphous drug. The combination of now small and amorphous drug embedded in the amorphous thin walled particle confers surprising solubility when compared to the bulk drug (p. 7-8, [0087]).

The compounds of the invention can be provided in various administration forms, including, for example, uncoated or (film-)coated tablets, capsules, powders, granules and the like as well as particle-filled capsules (p. 8, [0096-0097]). In one embodiment, the particles have a dissolution rate enhancement of at least 2-fold compared to the bulk drug (p. 9, [0098]); (p. 10, [0122]).

Suitable active compounds are disclosed at p. 9, [0101] and include, for instance, lansoprazole, olanzapine and the like.

Thus, Batycky discloses pharmaceutical dosage forms in the form of compressed tablets or powder/particle-filled capsules which contain poorly soluble active agents that would be susceptible to polymorphic conversion, and discloses that the process of formulating the dosage forms enables particles comprising the amorphous drug whereby bioactivity is not damaged and polymorphic stability is maintained. The instant specification, at page 2, lines 23-28, further evidences that "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms".

The instant claims are anticipated by Batycky.

4. Claims 1-3 and 8 are again rejected under 35 U.S.C. 102(e) as being anticipated by Babcock *et al.* (U.S. Pat. Appln. Pub. No. 2003/0104063).

Babcock *et al.* ('063) discloses pharmaceutical compositions comprising a dispersion of amorphous, low-solubility drugs combined with concentration-enhancing polymers for enhancing and improving the stability of a drug (see Abstract); (p. 1, [0002]-[0004]). Babcock discloses that a least a major portion of said drug in the dispersion is amorphous and is preferably almost completely amorphous, whereby the amount of drug in the amorphous form is at least 90% (p. 1, [0012-0014]); (p. 2 [0030]); (p. 59, [1211]. This reads on Applicant's limitation of claim 3. Suitable active agents disclosed include cholesterol-lowering agents and other low-solubility drugs (p. 4, [0052]); (p. 6-7, [0077-0080]). The pharmaceutical compositions may be prepared according to methods disclosed at p. 69, [1294-1298]. The compositions can be provided in various administration forms, including, for example, tablets, capsules, suspensions, powders, multiparticulates, pills and the like. Excipients can be mixed

with the concentration-enhancing polymer to form different beads, or layers or coatings or cores or separate dosage forms (p. 72, [01316]-[1319]); (p. 73, [1327]).

The instant claims are anticipated by Babcock.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3-5 and 9-20 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250).

Batycky *et al.* ('250), as discussed above, teaches particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

The particles of the invention have a mean particle size of about 5 to about 50 microns (p. 3, [0029]). The morphology of the instant particles contributes to enhanced dispersibility and stability by decreasing the area of contact between the particles (p. 3, [0030]). The particles can

deliver at least about 5 mg of the drug and the powder can be compressed about 10 to about 29 times. Even when compressed, the particles still retain the improvement in dissolution rate (p. 3, [0030]). Suitable excipients for use in the formulation are disclosed at p. 4, [0035-0037].

In one embodiment, the invention provides for an important feature for conferring pharamacokinetic/pharmacodynamic solubility to a poorly soluble drug, whereby the feature is dissolving a crystalline drug to form a solution and spray drying the solution thereby making the drug amorphous and small without damaging bioactivity and concurrently making the particle comprising the amorphous drug. The combination of now small and amorphous drug embedded in the amorphous thin walled particle confers surprising solubility when compared to the bulk drug (p. 7-8, [0087]).

The compounds of the invention can be provided in various administration forms, including, for example, uncoated or (film-)coated tablets, capsules, powders, granules and the like as well as particle-filled capsules (p. 8, [0096-0097]). In one embodiment, the particles have a dissolution rate enhancement of at least 2-fold compared to the bulk drug (p. 9, [0098]); (p. 10, [0122]).

Suitable active compounds are disclosed at p. 9, [0101] and include, for instance, lansoprazole, olanzapine and the like.

Thus, Batycky discloses pharmaceutical dosage forms in the form of compressed tablets or powder/particle-filled capsules which contain poorly soluble active agents that would be susceptible to polymorphic conversion, and discloses that the process of formulating the dosage forms enables particles comprising the amorphous drug whereby bioactivity is not damaged and polymorphic stability is maintained.

While Batycky does not explicitly teach the compression parameters of instant claims 4, 5, 9, 12, 14 and 18, the reference is nonetheless suggestive of formulations comprising amorphous drugs, whereby the particles, even when compressed, still retain the improvement in dissolution rate (p. 3, [0030]) and maintain polymorphic stability without damaging bioactivity. The formulation clearly provides for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]). Moreover, the determination of suitable or effective compression forces can be obtained by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Furthermore, the instant specification, at page 2, lines 23-28, further evidences that "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms".

With respect to the dimensions of the tablet ("about 3 mm" or "about 1 mm to about 3 mm") as in instant claims 13, 15 and 19, Batycky meets these limitations, as their particles have a mean particle size of about 5 to about 50 microns (p. 3, [0029]).

Regarding instant claim 17, Batycky teaches the use of both coated and uncoated tablets, as well as capsules, powders, granules and particle-filled capsules, for example (p. 8, [0096-0097]).

With respect to claim 9, which recites product-by-process limitations, the Examiner notes "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In any event, Batycky meets the product-by-process limitations, based on their teachings at (p. 1, [0010]; p. 2, [0014]), whereby the active agent is mixed with one or more excipients, as further discussed below.

With respect to claim 14, which recites a method of preparing the pharmaceutical dosage form, Batycky meets these limitations. Batycky discloses a method for preparation whereby the particles may comprise one or more drugs, wherein the drug forms a solid solution with one or more excipients, such as for example, where a drug is molecularly dispersed with one or more excipients and/or wherein a drug is present is regions of drug-rich material (p. 1, [0010]; p. 2, [0014]).

Regarding instant claims 2, 10 and 16, Batycky teaches active agents that are amorphous. See p. 9, [0101], whereby suitable active agents disclosed include lansoprazole, olanzapine and the like.

Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Batycky discussed above.

7. Claims 21-23 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Batycky *et al.* (U.S. Pat. Appln. Pub. No. 2003/0129250), as applied to claims 1, 3-5 and 9-20 above and further in view of Khanna *et al.* (U.S. Pat. Appln. Pub. No. 2008/0119654).

Batycky *et al.* ('250), as discussed above, teaches particulate compositions for improving solubility of poorly soluble compounds in which is included poorly soluble compounds into porous amorphous, low density particles. The particles are produced by spray drying a dilute solution comprising a poorly soluble compound and any desired excipients (see Abstract; page 2, [0026]). The instant formulation and method allows for improved dissolution of poorly soluble drugs without sacrificing targeted flowability, wettability, selective agglomeration or annealing, yield or polymorphic stability (p. 1, [0010-0011]).

Batycky teaches active agents that are amorphous. See p. 9, [0101], whereby suitable active agents disclosed include lansoprazole, olanzapine and the like.

Batycky does not teach esomeprazole magnesium (as in instant claims 21-23).

Khanna *et al.* ('654) teaches amorphous forms of esomeprazole salts, i.e., esomeprazole magnesium and methods for the preparation thereof (see Abstract); p.1, [0001-0010]. The pharmaceutical composition includes carriers, excipients and diluents (p. 1, [0012]. The pharmaceutical composition may be used in the treatment of gastric-related diseases (p. 2, [0023]. The compositions can be provided in various administration forms, including, for example, tablets, capsules, pills and the like (p. 2, [0031]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate active agents, such as esomeprazole magnesium, as taught by Khanna within the formulations of Batycky. One would do so with a reasonable expectation of success because Khanna discloses amorphous forms of esomeprazole salts, i.e., esomeprazole magnesium for the effective treatment of gastric-related diseases and evidences that it is well-

known to provide for cholesterol-reducing agents in amorphous forms. The expected result would be an improved pharmaceutical composition for the effective treatment of gastric-related disorders and conditions.

Response to Arguments

8. Applicant's arguments filed January 28, 2011 have been fully considered but they are not found persuasive.

Rejection under 35 U.S.C. 102(e) over Batycky et al.

9. Applicant argued, "Batycky et al. do not disclose a drug subject to polymorphic conversion considering the teachings regarding unchanged solubility and the absence of any information about polymorphic forms after compression. Also, Claim 1 applies to using a drug substance in any polymorphic form, crystalline or amorphous, which is subject to polymorphic conversion during compression. The applicant argues that Batycky et al. do not contain teachings that would apply to make a dosage form using a crystalline drug . Batycky et al. also do not discuss conditions for compression."

Applicant's arguments have been fully considered but were not persuasive. Claim 1 states the drug is susceptible to polymorphic conversion and is compressed using forces sufficiently low to maintain the drug in its original polymorphic form, but does not differentiate if this form is crystalline or amorphous. Therefore the drug can be in either form, since a crystalline form is not required by the claim. Batycky et al. disclose a drug in crystalline form which is added to a solution and sprayed dried to change the drug to an amorphous form while

maintaining bioactivity. See page 8, paragraph [0087]. Since the drug is available in both crystalline and amorphous form, and since polymorphism can occur between various crystalline forms, or between crystalline and amorphous form, the drug is considered to be susceptible to polymorphic conversion.

The argument that there is no evidence stating the drug particles in Batycky et al. are subject to conversion during compression was not persuasive because as claim 1 states, the drug is "susceptible" to polymorphic conversion, meaning it can undergo polymorphic conversion but does not have to. Claim 1 also does not differentiate when the conversion should occur (i.e., before compression, during compression, or after compression), therefore Batycky et al. do not need to disclose drug particles subject to conversion during compression.

As stated before, the instant application further evidences that "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms." Since claim 1 states compression forces should be low enough to maintain a drug in its original polymorphic form and Batycky et al. disclose the polymorphic form to be amorphous and that polymorphic stability is not sacrificed, the amorphous form is maintained during compression. Also, Batycky et al. are silent as to whether the amorphous form converts back to the crystalline form, further evidencing that the amorphous form is maintained during compression. Batycky et al. disclose the composition is formulated as a tablet. The art is replete with conventional tableting pressures which are all dependent on the desired tablet diameter and depth. Since it is known that the amorphous form of the drug is maintained after compression, and that compression parameters for tableting are commonly

known in the art, the compression parameters used in Batycky et al. are deemed sufficiently low. With that said no other compression conditions are necessitated by claim 1.

For these reasons, the rejection of record has been maintained.

Rejection under 35 U.S.C. 102(e) over Babcock et al.

10. Applicant argued, "Since the composition is stabilized it does not contain a drug susceptible to polymorphic conversion. Also, Babcock et al. do not teach compression parameters."

Applicant's arguments have been fully considered but were not persuasive. Babcock et al. disclose drugs that are polymorphic and can be either crystalline or amorphous. Stabilization allows for them to maintain a specified form over a longer period of time, however the polymorphic feature is still present and conversion is possible at any time. The instant application does not state that polymorphic conversion must occur, only that it is possible, therefore Babcock et al. read on these claims.

Applicant's argument that Babcock et al. do not teach compression parameters was not found persuasive because it is commonly known in the art that tablets are formed by compression. The art is replete with conventional tableting pressures based on the desired tablet dimensions (i.e., diameter and depth). The instant application states "It is known that amorphous materials frequently exhibit improved compression characteristics over the corresponding crystalline forms" and claim 1 states compression forces should be low enough to maintain a drug in its original polymorphic form. Since Babcock et al. disclose an amorphous form that is maintained during compression and Babcock et al. are silent as to whether the amorphous form is

converted to crystalline form after compression, then the resultant tablet would contain a drug in amorphous form.

For these reasons, the rejection of record has been maintained.

Rejection under 35 U.S.C. 103(a) over Batycky et al.

11. Applicant argued, "Rejection for obviousness is only proper if the differences are supplied by the state of the art. Also, even though there is an amorphous drug and matrix used to make a dosage form, the composition is not said to constitute a drug susceptible to polymorphic conversion. The determination of suitable or effective compression forces being done using routine experimentation is a result of impermissible hindsight analysis, since there is nothing on record to suggest that compression force has any effect on drug polymorphic conversion in a dosage form. The claim limitations about 3mm and about 1mm to about 3 mm are not met with powder particle sizes of about 5 to about 50 micron. In regards to claim 9, Applicant argues that mixing an active agent with one or more excipients as described by Batycky et al. do not account for the drug substance being susceptible to polymorphic conversion."

Applicant's arguments have been fully considered but were not persuasive. Applicant's argument that the rejection for obviousness could be proper only if those differences can somehow be supplied by the state of the art was not found persuasive because prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the

art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." Dann v. Johnston, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976).

Applicant's argument that the formation of an amorphous combination of a drug and matrix using spray drying can not be said to constitute the use of a drug substance that is susceptible to polymorphic conversion as required by claim 1 was not found persuasive because there is nothing in claim 1 that would preclude the drug from being in a matrix. Also, since Batycky et al. teach that the drug is amorphous and that polymorphic stability is maintained, there is nothing that would lead one to believe it is not susceptible to conversion unless evidenced to the contrary. Batycky et al. teach a crystalline drug that is sprayed dried into an amorphous form. This shows that the drug is polymorphic, meaning it is susceptible to conversion, but does not necessarily have to convert from one form to another.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's argument that 5 to about 50 micrometers do not fall within the limitation of about 3 mm and about 1 mm to about 3 mm was not found persuasive because the actual claims read "wherein a maximum tablet dimension is about 1 mm to about 3 mm" and "wherein a

maximum tablet dimension is about 3 mm". Therefore, 5 to about 50 micrometers fall within the range of a "**maximum** tablet dimension of about 1 mm to about 3 mm".

Applicant's argument that Batycky et al. do not teach a drug substance that is susceptible to polymorphic conversion in a method of mixing an active agent with one or more excipients was not found persuasive because Claim 9 is a product by process claim. Therefore, the important aspect in the claim is that a composition comprising a drug susceptible to polymorphic conversion is produced. The composition can contain any additional ingredients in any aspect of formulating the composition as long as the end product comprises a drug susceptible to polymorphic conversion. Since Batycky et al. teach a composition comprising an amorphous drug with polymorphic stability and excipients, it is deemed susceptible to polymorphic conversion because it has the potential to convert, but does not necessarily have to.

For these reasons, the rejection of record has been maintained.

Rejection under 35 U.S.C. 103(a) over Batycky et al. in view of Khanna et al.

12. Applicant argued, "There is no information regarding procedures for using the amorphous drug to prepare a dosage form and the teachings of Khanna et al. do not overcome differences in Batycky et al. as discussed above. Also, the Applicant states that it cannot be known whether the disclosed amorphous forms will be polymorphically stable or unstable during the formulation into a pharmaceutical dosage form."

Applicant's arguments have been fully considered but were not persuasive. The rejection of Batycky et al. were maintained above, therefore the limitations of claim 1 are covered by Batycky et al. Khanna et al. teach an amorphous form of esomeprazole which may be

formulated into a tablet. Since lansoprazole was used by Batycky et al. as a drug which maintained original polymorphic form after compression and lansoprazole is a proton pump inhibitor in the same class as omeprazole, then esomeprazole, the S-enantiomer of omeprazole, would also maintain its original polymorphic form. Since Khanna et al. teach that amorphous esomeprazole can be formulated into a tablet, and Batycky et al. teach methods of dosage formulation, it would have been obvious to formulate esomeprazole in the same manner as taught by Batycky et al.

In response to applicant's argument that claims 21-23 do not specify the use of amorphous esomeprazole magnesium, claims 21-23 do not preclude the use of amorphous esomeprazole. Therefore, unless evidenced to the contrary, either amorphous or crystalline esomeprazole magnesium could be used to meet the limitations of claims 21-23.

For these reasons, the rejection of record has been maintained.

Conclusion

13. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed at this time.

Correspondence

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA WORSHAM whose telephone number is 571-270-7434. The examiner can normally be reached on Monday - Thursday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JESSICA WORSHAM/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615